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PATENT

Attorney Docket No. P-162-US1

Customer No. 27038

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)	
Mathai MAMMEN et al.	) Gı	roup Art Unit: 1614
Application No.: 10/813,745	) ) Ex	caminer: Not yet assigned
Filed: March 31, 2004	· )	

Diarylmethyl And Related Compounds

## **INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure a soforth in 37 C.F.R. §1.56, Applicants respectfully submit this Information Disclosur DS) in conformance with 37 C.F.R. §§1.97 and 1.98 for the above-identified patent application. The documents being submitted for consideration by the Examiner are listed on the enclosed Form PTO/SB/08a.

The filing of this IDS shall not be construed as a representation that a search has been made (37 C.F.R. §1.97(g)), nor as an admission that the information submitted herewith is, or is considered to be, material to patentability (37 C.F.R. §1.97(h)) of the subject application.

Pursuant to 37 C.F.R. §1.98(a)(2)(ii), copies of U.S. patents and U.S. patent application publications cited on the accompanying PTO Form PTO/SB/08a are not being submitted. Copies of all other documents cited on the accompanying PTO Form PTO/SB/08a are enclosed herewith.

The following documents were cited in the International Search Report (ISR) for the corresponding PCT Patent Application No. PCT/US2004/009825 (a copy of the ISR is enclosed for the convenience of the Examiner):

- (1) U. S. Patent 6,433,027 B1 issued August 13, 2003;
- (2) International Publication 99/64031 A2, published December 16, 1999;
- (3) International Publication 99/64035 A1, published December 16, 1999;
- (4) International Publication 2004/074276 A, published September 2, 2004; and
- (5) EP 0 388 054 A1, issued September 19, 1990.

Pursuant to 37 C.F.R. §1.98(a)(3)(i), a concise explanation of the relevance of the following non-English language document is provided:

(1) WO 98/54167 A1 (in Japanese) discloses indole compounds which are described as highly selective M<sub>3</sub> muscarinic receptor antagonists. An English-language machine translation of this document is enclosed herewith.

Applicants respectfully request that the Examiner consider all of the documents cited on the accompanying PTO Form PTO/SB/08a. After such consideration, the Examiner is respectfully requested to return an initialed copy of the enclosed form PTO/SB/08a to Applicants with the next Office Action on the merits.

This IDS is being filed before the mailing date of a first Office Action on the merits for this application and therefore, no fee or certification is required under 37 C.F.R. §1.97(b). In the event that an Office Action is mailed prior to receipt of this paper, the Commissioner is hereby authorized to charge any requisite fees for submission of this paper to Deposit Account No. 50-0344.

Any questions regarding this IDS should be directed to undersigned attorney for Applicants at (650) 808-6406 (direct).

Respectfully submitted,

THERAVANCE, INC.

Date: December 13, 2004

THERAVANCE, INC. 901 Gateway Boulevard South San Francisco, CA 94080

Tel: (650) 808-6000 Fax: (650) 808-6078 Bv:

offrey A. Nagenah, Ph. I

gistration No. 35,175

PTO/SB/08a (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE er the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute	e for form 1449A/PTC	)		Complete if Known		
				Application Number	10/813,745	
INFO	RMATION	DIS	CLOSURE	Filing Date	March 31, 2004	
STATEMENT BY APPLICANT		First Named Inventor	Mathai MAMMEN			
				Art Unit	1614	
(Use as many sheets as necessary)			necessary)	Examiner Name	Not yet assigned	
Sheet 1 of 2		Attorney Docket Number	P-162-US1			

	U.S. PATENT DOCUMENTS							
Examiner Initials *	Cite No.1	Document Number  Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
	A1	US- 3,192,210	06-29-1965	Lunsford et al.				
	A2	US- 3,192,221	06-29-1965	Lunsford et al.				
	A3	US- 3,247,222	04-19-1966	Lunsford				
	A4	US- 3,732,247	05-08-1973	Helsley et al.				
-	A5	US- 3.984,557	10-05-1976	Welstead, Jr.				
	A6	US- 4,002,766	01-11-1977	Welstead, Jr.				
	A7	US- 4,026,897	05-31-1977	Nakagawa et al.				
	A8	US- 4,460,581	07-17-1984	Schromm et al.				
	A9	US- 4,594,343	06-10-1986	Shanklin, Jr.				
	A10	US- 4,810,713	03-07-1989	Yanni et al.				
-	A11	US- 4,894,219	01-16-1990	Baker et al.				
	A12	US- 4,950,674	08-21-1990	Yanni et al.				
	A13	US- 4,992,474	02-12-1991	Skidmore et al.				
	A14	US- 5,070,087	12-03-1991	Teng et al.				
	A15	US- 5,096,890	03-17-1992	Cross et al.				
	A16	US- 5,233,053	08-03-1993	Cross et al.				
	A17	US- 5,340,831	08-23-1994	Cross et al.				
	A18	US- 5,607,950	03-04-1997	Alker et al.				
	A19	US- 5,932,594	08-03-1999	Cross et al.				
	A20	US- 6,268,533 B1	07-31-2001	Gao et al.				
	A21	US- 6,362,371 B1	03-26-2002	Moran et al.				
	A22	US- 6,433,027 B1	08-13-2002	Bozung et al.				
	A23	US- 6,541,669 B1	04-01-2003	Moran et al.				
	A24	US-6,576,793 B1	06-10-2003	Moran et al.				
	A25	US- 6,593,497 B1	07-15-2003	Choi et al.				
	A26	US- 6,653,323 B2	11-25-2003	Moran et al.				
	A27	US- 6,670,376 B1	12-30-2003	Moran et al.				
	A28	US- 6,693,202 B1	02-17-2004	Aggen et al.				
	A29	US- 6,713,651 B1	03-30-2004	Moran et al.				
	A30	US- 6,747,043 B2	06-08-2004	Moran et al.				
	A31	US- 2003/0018019 A1	01-23-2003	Meade et al.				

Examiner	Date	
Signature	 Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08a (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

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Substitut	te for form 1449A/PT	то		Complete if Known		
		Application Number	10/813,745			
INFORMATION DISCLOSURE			CLOSURE	Filing Date	March 31, 2004	
		First Named Inventor	Mathai MAMMEN			
		Art Unit	1614			
		Examiner Name	Not yet assigned			
Sheet	2	of	2	Attorney Docket Number	P-162-US1	

	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document  Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>			
	B1	WO 91/09013 A1	06-27-1991	Pfizer Limited					
	B2	WO 98/54167 A1 (in Japanese with English translation)	12-3-1998	Tokyo Tanabe Company Ltd		<b>/</b>			
	B3	WO 99/64031 A1	12-16-1999	Advanced Medicine, Inc.					
	B4	WO 99/64035 A1	12-16-1999	Advanced Medicine, Inc.					
	B5	WO 99/64043 A1	12-16-1999	Advanced Medicine, Inc.					
	B6	WO 02/066422 A1	08-29-2002	Glaxo Group Ltd					
	B7	WO 2004/074276 A1	09-02-2004	Theravance, Inc.					
	B8	EP 0 178 946 A2	04-23-1986	A. H. Robins Co, Inc.					
	B9	EP 0 178 947 A2	04-23-1986	A. H. Robins Co., Inc.					
	B10	EP 0 235 463 A2	09-09-1987	A. H. Robins Co., Inc.					
	B11	EP 0 388 054 A1	09-19-1990	Pfizer Limited					
	B12	DE 25 58 501	07-08-1976	A. H. Robins Co., Inc.					

NON PATENT LITERATURE DOCUMENTS						
C1	CALE et al., "A Series of Central Nervous System Stimulants Based on the 4-Substituted 3,3-Diphenyl-2-pyrrolidinone Skeleton. II", J. Med. Chem., 10(2), pp 214-222 (1967)					
C2	GLAXO WELLCOME PLC, New long acting ß <sub>2</sub> agonists", Expert Opin. Ther. Patents, 13(2), pp 273-277 (2003)	<u> </u>				
СЗ	GRAUL et al., "Darifenacin", Drugs of the Future, 21(11), pp 1105-1108 (1996)					
C4	MILECKI et al., "Carbostyril Derivatives Having Potent ß-Adrenergic Agonist Properties", J.Med. Chem., 30, pp 1563-1566 (1987)	-				
C5	ZLOTOS et al., "Muscarinic receptor agonists and antagonists", Exp. Opin. Ther. Patents, 9(8), pp 1029-1053 (1999)					
	No. <sup>1</sup> C1 C2 C3 C4	Cite No.1  Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.  C1  CALE et al., "A Series of Central Nervous System Stimulants Based on the 4-Substituted 3,3-Diphenyl-2-pyrrolidinone Skeleton. II", J. Med. Chem., 10(2), pp 214-222 (1967)  C2  GLAXO WELLCOME PLC, New long acting \( \mathbb{G}_2 \) agonists", Expert Opin. Ther. Patents, 13(2), pp 273-277 (2003)  C3  GRAUL et al., "Darifenacin", Drugs of the Future, 21(11), pp 1105-1108 (1996)  C4  MILECKI et al., "Carbostyril Derivatives Having Potent \( \mathbb{G}_2 \)-Adrenergic Agonist Properties", J.Med. Chem., 30, pp 1563-1566 (1987)  ZLOTOS et al., "Muscarinic receptor agonists and antagonists", Exp. Opin. Ther. Patents, 9(8), pp 1029-1053				

Examiner		Date		1
Signature		Considered		
<u> </u>	 		L	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.